

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE LITIGATION

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)  
) MDL NO. 1456

) Civil Action No. 01-12257-PBS

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THIS DOCUMENT RELATES TO:

)  
) Judge Patti B. Saris

*The City of New York v. Abbott Laboratories, Inc., et al.*  
(S.D.N.Y. No. 04-CV-06054)

*County of Albany v. Abbott Laboratories, Inc., et al.*  
(N.D.N.Y. No. 05-CV-00425)

*County of Allegany v. Abbott Laboratories, Inc., et al.*  
(W.D.N.Y. No. 05-CV-06231)

*County of Broome v. Abbott Laboratories, Inc., et al.*  
(N.D.N.Y. No. 05-CV-00456)

*County of Cattaraugus v. Abbott Laboratories, Inc., et al.*  
(W.D.N.Y. No. 05-CV-06242)

*County of Cayuga v. Abbott Laboratories, Inc., et al.*  
(N.D.N.Y. No. 05-CV-00423)

*County of Chautauqua v. Abbott Laboratories, Inc., et al.*  
(W.D.N.Y. No. 05-CV-06204)

*County of Chemung v. Abbott Laboratories, Inc., et al.*  
(W.D.N.Y. No. 05-CV-06744)

*County of Chenango v. Abbott Laboratories, Inc., et al.*  
(N.D.N.Y. No. 05-CV-00354)

*County of Columbia v. Abbott Laboratories, Inc., et al.*  
(N.D.N.Y. No. 05-CV-00867)

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**ANSWER AND AFFIRMATIVE DEFENSES OF TAP PHARMACEUTICAL  
PRODUCTS INC. TO REVISED FIRST AMENDED CONSOLIDATED COMPLAINT**

*County of Cortland v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00881)

*County of Dutchess v. Abbott Laboratories, Inc., et al.* )  
(S.D.N.Y. No. 05-CV-06458)

*County of Essex County v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00878)

*County of Fulton v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00519)

*County of Genesee v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06206)

*County of Greene v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00474)

*County of Herkimer v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00415)

*County of Jefferson v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00715)

*County of Lewis v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00839)

*County of Madison v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00714)

*County of Monroe v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06148)

*County of Nassau v. Abbott Laboratories, Inc., et al.* )  
(E.D.N.Y. No. 04-CV-5126)

*County of Niagara v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06296)

*County of Oneida v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00489)

*County of Onondaga v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00088)

*County of Ontario v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06373)

*County of Orange v. Abbott Laboratories, Inc., et al.* )  
(S.D.N.Y. No. 07-CV-2777)

*County of Orleans v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06371)

*County of Putnam v. Abbott Laboratories, Inc., et al.* )  
(S.D.N.Y. No. 05-CV-04740)

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*County of Rensselaer v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00422)

*County of Rockland v. Abbott Laboratories, Inc., et al.* )  
(S.D.N.Y. No. 03-CV-7055)

*County of Saratoga v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00478)

*County of Schuyler v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06387)

*County of Seneca v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06370)

*County of St. Lawrence v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00479)

*County of Steuben v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06223)

*County of Suffolk v. Abbott Laboratories, Inc., et al.* )  
(E.D.N.Y. No. CV-03-229)

*County of Tompkins v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00397)

*County of Ulster v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 06-CV-0123)

*County of Warren v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00468)

*County of Washington v. Abbott Laboratories, Inc., et al.* )  
(N.D.N.Y. No. 05-CV-00408)

*County of Wayne v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06138)

*County of Westchester v. Abbott Laboratories, Inc., et al.* )  
(S.D.N.Y. No. 03-CV-6178)

*County of Wyoming v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 03-CV-6379)

AND )

*County of Yates v. Abbott Laboratories, Inc., et al.* )  
(W.D.N.Y. No. 05-CV-06172)

Defendant TAP Pharmaceutical Products Inc. ( “TAP”), by and through its attorney, hereby states as its Answer and Affirmative Defenses to the Revised First Amended Consolidated Complaint, dated October 5, 2001, as follows:

**PRELIMINARY STATEMENT**

This answer in no way responds to the Plaintiffs’ First Amended Consolidated Complaint (the “Complaint”) to the extent it claims to bring causes of action against TAP with respect to the drug Lupron<sup>®</sup>. On March 3, 2006, TAP, in addition to joining the Defendants in a Joint Motion to Dismiss, filed its own Supplemental Memorandum in Support of Defendants’ Joint Motion to Dismiss, seeking to dismiss all claims related to its drug Lupron<sup>®</sup> on the basis that such claims were settled, dismissed, released and otherwise disposed of by 2001 and 2005 Settlement Agreements and are therefore barred. After the filing of the parties’ various responses to the Joint Motion to Dismiss, this Court on April 2, 2007 ruled on the Defendants’ Joint Motion to Dismiss, but did not rule on TAP’s individual motion. Thereafter, on June 8, 2007, the Plaintiffs filed the Complaint. Rather than re-filing the same motion to dismiss, TAP filed a Motion to Renew the Supplemental Motion and Reasserts its Reply on June 22, 2007. Plaintiffs filed their Opposition on July 11, 2007 and TAP responded on July 18, 2007. This Court has not yet ruled on these motions. Given that TAP has an outstanding motion to dismiss pending before this court, this answer is limited to Plaintiffs’ claims related to those drugs specified on Revised Exhibit B to the Complaint other than Lupron<sup>®</sup>.

Additionally, the Complaint improperly refers to TAP, other defendants, and third parties on a collective basis, failing to plead with requisite particularity allegations against TAP. This is insufficient to apprise TAP (let alone each separate entity) of the allegations asserted against it. TAP has nevertheless attempted to respond to Plaintiffs’ allegations to the extent

possible. To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of other persons or entities, TAP is generally without knowledge or information sufficient to form a belief as to the truth of those allegations. TAP states that it is answering Plaintiffs' allegations solely on behalf of itself, even when Plaintiffs' allegations refer to alleged conduct by TAP and other persons or entities.

The Complaint also contains purported quotations from a number of sources. In answering allegations consisting of quotations, TAP's failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or TAP's reference to the full document instead of the quote shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

TAP denies each and every allegation contained in the Complaint and the exhibits thereto, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculation contained in any particular averment or in the Complaint as a whole. In addition, TAP specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, TAP has included in this Answer and Affirmative Defenses the caption used in the Complaint, but specifically denies any allegations contained in, or inferences that could be drawn from, that caption.

These comments and objections are incorporated, to the extent appropriate, into each unnumbered and numbered paragraph of this Answer.

## **SPECIFIC RESPONSES**

To the extent that the unnumbered paragraph immediately following the Table of Contents (the “Complaint’s Introductory Paragraph”) makes allegations against TAP, TAP denies them, except admits that the City of New York and certain New York Counties (collectively, the “Counties”) have made allegations against a number of defendants, including TAP, as set forth in the Complaint. To the extent that the Complaint’s Introductory Paragraph states legal conclusions, no response is required. To the extent the allegations of the Complaint’s Introductory Paragraph are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations.

1. TAP admits that the Counties seek to bring this action as alleged in Paragraph 1 of the Complaint, but TAP denies there is any basis for them to do so and denies that they are entitled to any relief. TAP also admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies any liability to Plaintiffs with respect to any such NDCs. To the extent the remaining allegations in Paragraph 1 are directed at TAP, TAP denies them. TAP specifically denies that it has been involved in “fraudulent and misleading schemes” or that the New York State Medicaid Program has been “overcharge[d]” for prescription drugs. To the extent the remaining allegations in Paragraph 1 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

2. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 or the exhibit referenced therein. To the extent the allegations in

Paragraph 2 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

3. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 or its footnote, except admits that it pays Medicaid rebates to the State of New York and that such rebates lower the overall price New York Medicaid pays for TAP's prescription drugs. To the extent the allegations in Paragraph 3 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

4. To the extent the allegations in Paragraph 4 are directed at TAP, TAP denies them. TAP specifically denies that it was involved in "fraudulent schemes," the "manipulation of the Medicaid program" or the "intentional fraudulent inflation" of wholesale prices, or that the Counties' Medicaid Programs were "overcharge[d]." To the extent the allegations in Paragraph 4 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

5. To the extent the allegations in Paragraph 5 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. TAP otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5.

6. To the extent the allegations in Paragraph 6 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. TAP otherwise denies knowledge or information sufficient to form a belief as to the truth of the

allegations in Paragraph 6 or its footnote, except TAP denies that it “actively encourage[s] physicians to write DAW in order to secure AWP-based reimbursement for pharmacies.”

7. To the extent the allegations in Paragraph 7 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. TAP otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7.

8. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8.

9. To the extent the allegations in Paragraph 9 are directed at TAP, TAP denies them. TAP specifically denies that it “control[s] and unlawfully inflates[s]” average wholesale prices (“AWPs”) or federal upper limits (“FULs”). To the extent the allegations in Paragraph 9 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

10. To the extent the allegations in Paragraph 10 are directed at TAP, TAP denies them, except TAP admits that it has provided the wholesale acquisition cost of its drugs to certain industry pricing compendia and that publishers apply their own markups to the list prices. TAP specifically denies that it “set[s] AWP.” To the extent the allegations in Paragraph 10 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.



11. To the extent the allegations in Paragraph 11 are directed at TAP, TAP denies them. To the extent the allegations in Paragraph 11 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

12. To the extent the allegations in Paragraph 12 or the exhibit referenced therein are directed at TAP, TAP denies them. TAP specifically denies that it has “report[ed] a false and inflated WAC or WAC equivalent” to industry pricing compendia. To the extent the allegations in Paragraph 12 or the exhibit referenced therein are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

13. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding CMS’s setting of FULs for certain drugs. To the extent the remaining allegations in Paragraph 13 are directed at TAP, TAP denies them, TAP specifically denies that it “control[s] the FUL.” To the extent the allegations in Paragraph 13 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 13 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

14. To the extent the allegations in Paragraph 14 are directed at TAP, TAP denies them. TAP further states that, the TAP drugs at issue in this case are single-source drugs not subject to FULs. To the extent the allegations in Paragraph 14 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

15. To the extent the allegations in Paragraph 15 or the exhibit referenced therein are directed at TAP, TAP denies them. To the extent the allegations in Paragraph 15 or the exhibit

referenced therein are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

16.-17. To the extent the allegations in Paragraphs 16-17 are directed at TAP, TAP denies them. TAP specifically denies that it “submit[s] false and inflated price information to the publishing compendia.” TAP further denies the characterization of “spread” in Paragraphs 16-

17. To the extent the allegations in Paragraphs 16-17 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

18.-19. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 18-19.

20. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20. To the extent the allegations in Paragraph 20 refer to a Wall Street Journal article, the article speaks for itself, and any characterizations thereof are denied.

21. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21 or the exhibit referenced therein.

22. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22.

23. To the extent the allegations in Paragraph 23 are directed at TAP, TAP denies them. TAP specifically denies that it has “secretly polluted the entire reimbursement system with false and inflated prices.” To the extent the allegations in Paragraph 23 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

24. To the extent the allegations in Paragraph 24 or the exhibit referenced therein are directed at TAP, TAP denies them. TAP specifically denies that it has “cause[d] false and inflated published reimbursement prices to issue.” TAP further denies the characterization of “spread” in Paragraph 24. To the extent the allegations in Paragraph 24 or the exhibit referenced therein are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

25. To the extent the allegations in Paragraph 25 are directed at TAP, TAP denies them. TAP specifically denies that it has “create[d], inflate[d], manipulate[d] and market[ed] the spread for both brand name and generic drugs.” To the extent the allegations in Paragraph 25 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

26. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26. To the extent the allegations in Paragraph 26 refer to an HHS OIG report, the report speaks for itself, and any characterizations thereof are denied.

27. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27. To the extent the allegations in Paragraph 27 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

28. To the extent the allegations in Paragraph 28 or the exhibit referenced therein are directed at TAP, TAP denies them. TAP specifically denies that it has engaged in “intentional AWP inflation” or “fraud.” TAP further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the

Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraph 28 or the exhibit referenced therein are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

29. To the extent the allegations in Paragraph 29 are directed at TAP, TAP denies them. TAP specifically denies that it has “reported or caused to be reported [] false and inflated” WACs or engaged in any “unlawful and undisclosed manipulation of the price reporting system.” To the extent the allegations in Paragraph 29 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

30. To the extent the allegations in Paragraph 30 or the exhibit referenced therein are directed at TAP, TAP denies them. TAP specifically denies that it has engaged in any “pricing misconduct.” TAP further states that, the TAP drugs at issue in this case are singles-source drugs not subject to FULs. To the extent the allegations in Paragraph 30 or the exhibit referenced therein are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

31. To the extent the allegations in Paragraph 31 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. TAP otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 or its footnote, except TAP admits that it pays Medicaid rebates as required by law.

32. To the extent the allegations in Paragraph 32 are directed at TAP, TAP denies them. To the extent the allegations in Paragraph 32 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

33. To the extent the allegations in Paragraph 33 or its footnote are directed at TAP, TAP denies them. TAP specifically denies that it “ma[d]e unlawful use of the so-called ‘nominal price’ exception” or has “abused” any Medicaid statute. To the extent the allegations in Paragraph 33 or its footnote are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 33 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

34. To the extent the allegations in Paragraph 34 are directed at TAP, TAP denies them. To the extent the allegations in Paragraph 34 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 34 refer to an HHS OIG report, the report speaks for itself, and any characterizations thereof are denied.

35. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35.

36. TAP admits that, in 2001, it paid approximately \$875 million in fines and civil settlements related to its sale and marketing of the drug Lupron<sup>®</sup>, but further states that to the extent that Paragraph 36 refers to the drug Lupron<sup>®</sup>, any response to this allegation would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron<sup>®</sup>. To the extent the allegations in Paragraph 36 or the exhibit

referenced therein are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

37. TAP admits that the Counties seeks the relief listed in Paragraph 37, but TAP denies there is any basis for them to do so and denies that they are entitled to any relief. To the extent the remaining allegations in Paragraph 37 are directed at TAP, TAP denies them. TAP specifically denies that it has been involved in any “fraudulent and illegal manipulation of drug prices.” To the extent the remaining allegations in Paragraph 37 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

38. TAP admits that the Counties seek to bring this action as alleged in Paragraph 38, but TAP denies there is any basis for them to do so and denies that they are entitled to any relief.

39.-40. Paragraphs 39-40 state legal conclusions as to which no response is required. To the extent a response is deemed to be required, TAP denies the allegations in Paragraphs 39-40, except admits that each of the captioned matters has been transferred to this Court by the Judicial Panel on Multi District Litigation pursuant to 28 U.S.C. 1407.

41.-42A. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 41- 42A. To the extent the allegations in Paragraphs 41-42A refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

43. TAP denies the allegations in Paragraph 43 and its footnote, and refers to Case Management Order No. 33, dated September 14, 2007, ¶¶ 1, 3 for which plaintiffs are suing which defendants.

44. To the extent the allegations in Paragraph 44 are directed at TAP, TAP denies them, except TAP admits that it sells prescription drugs and that it transacts business in the State and City of New York. TAP specifically denies that it “manufactures, markets and sells prescription drugs with false and inflated wholesale prices.” To the extent the allegations in Paragraph 44 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

45.-79. The allegations in Paragraphs 45-79 are directed to other defendants and require no response from TAP. To the extent a response is deemed to be required, TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 45-79.

80. With respect to the allegations in Paragraph 80 and the sub-parts thereof, TAP admits that TAP Pharmaceutical Products Inc. is a joint venture between and its stock is half-owned by each of Abbott Laboratories and Takeda Pharmaceutical Company Limited of Osaka, Japan. TAP admits that it is “engaged in the business of . . . selling pharmaceuticals,” but denies it is in the “business of manufacturing . . . pharmaceuticals.” TAP admits that its principal place of business is located at 675 North Field Drive, Lake Forest, IL 60045. TAP otherwise denies the allegations in Paragraph 80 of the Complaint.

81.-84. The allegations in Paragraphs 81-84 are directed to other defendants and require no response from TAP. To the extent a response is deemed to be required, TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 81-84.

85.-88. The allegations in Paragraphs 85-88 are directed to unknown defendants and require no response from TAP. To the extent a response is deemed to be required, TAP denies that it was involved in any conspiracy related to drug pricing with either named or unknown defendants. TAP also denies that it has engaged in any “wrongful acts” related to drug pricing.

89. With respect to the allegations in Paragraph 89, TAP admits that Medicaid was established by Title XIX of the Social Security Act. TAP further states that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.

90. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 90, except TAP admits that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 90 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

91.-99. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 91-99 or their footnotes. To the extent the allegations in Paragraphs 91-99 or their footnotes refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

100. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 100, except admits that national drug codes are assigned to prescription drugs and that the FDA assigns such codes.

101.-111. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 101-111 or their footnotes. To the extent the allegations in



Paragraphs 101-111 or their footnotes refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

112. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 112, except admits that pricing compendia, such as Blue Book, publish AWP and denies that TAP has any control over such prices.

113. To the extent the allegations in Paragraph 113 are directed at TAP, TAP denies them. TAP specifically denies that it has “fraudulently conceal[ed]” the “true prices” of its drugs by “claiming they are proprietary trade secrets.” To the extent the allegations in Paragraph 113 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 113 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

114.-115. To the extent the allegations in Paragraphs 114-115 are directed at TAP, TAP denies them. TAP specifically denies that it reports “reimbursement prices . . . to the publishing compendia” or that it has engaged in the “purposeful manipulation of reimbursement prices generally, and AWP in particular.” TAP further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraphs 114-115 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in

Paragraphs 114-115 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

116.-123. With respect to the allegations in Paragraphs 116-123 and their footnotes, TAP admits that the Medicaid statute includes a rebate provision, that it has entered into a rebate agreement with the Secretary of Health and Human Services, and that rebates help reduce state Medicaid drug expenditures. TAP further states that the rebate provision speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 116-123 or their footnotes refer to additional statutes, regulations or congressional reports, those sources also speak for themselves, and any characterizations thereof are also denied.

124.-125. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 124-125. To the extent the allegations in Paragraphs 124-125 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. TAP denies that the Counties are intended third-party beneficiaries of Medicaid rebate agreements.

126. With respect to the allegations in Paragraph 126, TAP admits that drug manufacturers report Best Prices and AMPs to HHS. To the extent the allegations in Paragraph 126 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

127.-130. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 127-130, except admits that it reports Medicaid information to HHS and pays rebates to States. To the extent the allegations in Paragraphs 127-130 refer to statutes,

regulations or amicus briefs filed by the United States, those sources speak for themselves, and any characterizations thereof are denied.

131. To the extent the allegations in Paragraph 131 are directed at TAP, TAP denies them. To the extent the allegations in Paragraph 131 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 131 refer to the Model Rebate Agreement, that document speaks for itself, and any characterizations thereof are denied.

132. To the extent the allegations in Paragraph 132 are directed at TAP, TAP admits that it has executed a rebate agreement with HHS. TAP further states that the rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraph 132 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 132 refer to the Model Rebate Agreement, that document also speaks for itself, and any characterizations thereof are also denied.

133.-136. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 133-136. To the extent the allegations in Paragraphs 133-136 refer to the Model Rebate Agreement, that document speaks for itself, and any characterizations thereof are denied.

137.-143. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 137-143, except TAP denies that the Counties are Medicaid payors or intended third-party beneficiaries of Medicaid rebate agreements. To the extent the

allegations in Paragraphs 137-143 refer to statutes, regulations or amicus briefs filed by the United States, those sources speak for themselves, and any characterizations thereof are denied.

144. To the extent the allegations in Paragraph 144 are directed at TAP, TAP denies them. TAP specifically denies that it “intentionally reported, or caused to be reported, to industry publications wholesale pricing information that it knew to be false and inflated.” TAP further denies the characterization of “spread” in Paragraph 144. To the extent the allegations in Paragraph 144 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

145.-149. With respect to the allegations in Paragraphs 145-149, TAP admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein. To the extent the remaining allegations in Paragraphs 145-149 or Exhibit B are directed at TAP, TAP denies them. TAP specifically denies that it “purposeful[ly] submit[ted] [] false and inflated reimbursement price information” or “routinely submitted fraudulent prices” to pricing compendia. TAP further denies the characterization of “spread” in Paragraphs 145-149 and Exhibit B. To the extent the remaining allegations in Paragraphs 145-149 or Exhibit B are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

150.-151. To the extent the allegations in Paragraphs 150-151 are directed at TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. TAP further states that the TAP drugs at issue in this case are single-source drugs. To the extent the remaining allegations in Paragraphs 150-151 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

152.-153. To the extent the allegations in Paragraphs 152-153 are directed at TAP, TAP denies them. TAP further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraphs 152-153 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

154. Paragraph 154 purports to contain a statement from HHS OIG, but TAP denies knowledge or information sufficient to form a belief as to its accuracy because the source thereof is not provided. To the extent the source of the statement is provided, the source speaks for itself, and any characterizations thereof are denied.

155.-158. To the extent the allegations in Paragraphs 155-158 are directed at TAP, TAP denies them. TAP further states that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraphs 155-158 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

159.-165. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 159-165, except TAP admits that PBMs are involved in administering and managing prescription drug benefit programs and that certain PBMs also operate mail order pharmacies. To the extent the allegations in Paragraphs 159-165 refer to

articles or reports, those sources speak for themselves, and any characterizations thereof are denied.

166. To the extent the allegations in Paragraph 166 are directed at TAP, TAP denies them. TAP specifically denies that it “control[s] the published reimbursement prices.” To the extent the allegations in Paragraph 166 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

167. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 167.

168.-172. To the extent the allegations in Paragraphs 168-172 are directed at TAP, TAP denies them, except TAP admits that it has executed a rebate agreement with HHS. TAP further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to TAP. In any event, the rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 168-172 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 168-172 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

173.-176. To the extent the allegations in Paragraphs 173-176 are directed at TAP, TAP denies them, and further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to TAP. To the extent the allegations in Paragraphs 173-176 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 173-176 refer to statutes,

regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

177. To the extent the allegations in Paragraph 177 are directed at TAP, TAP denies them. To the extent the allegations in Paragraph 177 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

178.-194. To the extent the allegations in Paragraphs 178-194 or their footnotes are directed at TAP, TAP denies them. To the extent the allegations in Paragraphs 178-194 or their footnotes are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 178-194 or their footnotes refer to reports, articles, letters, congressional hearing transcripts, or other documents, those sources speak for themselves, and any characterizations thereof are denied.

195. To the extent the allegations in Paragraph 195 are directed at TAP, TAP denies them, except TAP admits that its contracts with purchasers sometimes included discounts. To the extent the allegations in Paragraph 195 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

196. To the extent the allegations in Paragraph 196 or the exhibit referenced therein are directed at TAP, TAP denies them. To the extent the allegations in Paragraph 196 or the exhibit referenced therein are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

197.-699. The allegations in Paragraphs 197-699 are directed to other defendants and require no response from TAP. To the extent a response is deemed to be required, TAP denies

knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 197-699.

700. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 700 or its footnote or the exhibit referenced therein and states that Exhibit B to the Complaint has changed since the filing of the Complaint.

701. TAP denies the allegations in Paragraph 701 and the exhibit referenced therein, and states that Exhibit B to the Complaint has changed since the filing of the Complaint.

702. TAP admits that its stock is half owned by each of Takeda Pharmaceutical Company Limited and Abbott Laboratories, that it was investigated by the Department of Justice and that, on October 13, 2001, the Department of Justice announced that TAP had agreed to pay approximately \$875 million in settlement of criminal charges and civil claims related to the sale and marketing of the drug Lupron<sup>®</sup>, but states that its plea agreement and civil settlement agreements speak for themselves and denies any allegations or characterizations inconsistent therewith. TAP further states that to the extent that Paragraph 702 refers to the drug Lupron<sup>®</sup>, any response to this allegation would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron<sup>®</sup>. TAP denies the remaining allegations of Paragraph 702.

703. TAP admits that it pled guilty to an indictment charging a one count conspiracy to violate the Prescription Drug Marketing Act and that it paid a criminal fine of \$290 million, but states that its plea agreement and civil settlement agreements speak for themselves and denies any allegations or characterizations inconsistent therewith. TAP further states that to the extent that Paragraph 703 refers to the drug Lupron<sup>®</sup>, any response to this allegation would be



premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron<sup>®</sup>. TAP denies the remaining allegations of Paragraph 703.

704. TAP admits that it paid approximately \$560 million in settlement of claims by the United States government related to the sale and marketing of the drug Lupron<sup>®</sup>, but states that its plea agreement and civil settlement agreements speak for themselves and denies any allegations or characterizations inconsistent therewith. TAP further states that to the extent that Paragraph 704 refers to the drug Lupron<sup>®</sup>, any response to this allegation would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron<sup>®</sup>. TAP denies the remaining allegations of Paragraph 704.

705. TAP admits that it paid approximately \$25 million in settlement of claims to the fifty states and the District of Columbia related to sale and marketing of the drug Lupron<sup>®</sup>, but states that its plea agreement and civil settlement agreements speak for themselves and denies any allegations or characterizations inconsistent therewith. TAP further states that to the extent that Paragraph 705 refers to the drug Lupron<sup>®</sup>, any response to this allegation would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron<sup>®</sup>. TAP denies the remaining allegations of Paragraph 705.

706. TAP admits that it entered into a Corporate Integrity Agreement, which provided that it disclose the Average Sales Prices for all of its products quarterly to the states, CMS and First DataBank, but states that such agreement speaks for itself and denies any allegations or characterizations inconsistent therewith. TAP further states that to the extent that Paragraph 706 refers to the drug Lupron<sup>®</sup>, any response to this allegation would be premature given that there is

a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron®. TAP denies the remaining allegations of Paragraph 706.

707. TAP admits that in connection with TAP's guilty plea agreement, Abbott and Takeda entered into side letter agreements with the government in which they agreed to cooperate fully with the then ongoing investigation of TAP's former and current officers and employees. TAP further states that to the extent that Paragraph 707 refers to the drug Lupron®, any response to this allegation would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron®. TAP denies the remaining allegations of Paragraph 707.

708. TAP admits that former and current TAP employees were indicted on charges related to the sale and marketing of the drug Lupron®, that one employee entered a guilty plea that was later withdrawn and that the others were acquitted in 2004 after trial. TAP further states that to the extent that Paragraph 708 refers to the drug Lupron®, any response to this allegation would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron®. TAP denies the remaining allegations of Paragraph 708.

709. TAP admits that the allegations in Paragraph 709 purport to quote the cited transcript, but states that the record speaks for itself and denies any characterizations or misstatements thereof. TAP further states that to the extent that Paragraph 709 refers to the drug Lupron®, any response to this allegation would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron®. TAP denies the remaining allegations of Paragraph 709.

710. TAP admits that it was a defendant in the Russano v. Abbott Laboratories, No. 01-6982 (N.D. Ill., filed Sept. 7, 2001) and that action was settled and dismissed. TAP further states that to the extent that Paragraph 710 refers to the drug Lupron<sup>®</sup>, any response to this allegation would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron<sup>®</sup>. TAP denies the remaining allegations of Paragraph 710.

711. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 711.

712. TAP denies the allegations in Paragraph 712, except that it admits that it was named as a defendant in a Qui Tam action, denies there was any basis for said action, denies that the plaintiff was entitled to any relief and further states that the action was dismissed by the court. To the extent the allegations in Paragraph 712 or its footnote refer to “publicly filed exhibits,” those sources speak for themselves, and any characterizations thereof are denied.

713. TAP admits that it was named as a defendant in a Qui Tam action filed in Louisiana and that the allegations of the complaint in such action speak for themselves and denies any allegation or characterization inconsistent therewith. TAP further denies there was any basis for said action, denies that the plaintiff was entitled to any relief and further states that the action was dismissed by the court. TAP denies any remaining allegations in paragraph 713.

714. TAP denies the allegations in Paragraph 714.

715. TAP denies the allegations in Paragraph 715. TAP further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally

understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

716. TAP denies the allegations in Paragraph 716.

717. With respect to the allegations in Paragraph 717, TAP admits that it has been sued by the Attorneys General of Illinois, Kentucky, Pennsylvania and Wisconsin but denies there is any basis for those lawsuits. TAP further denies that it has engaged in any “wrongful conduct.”

718. To the extent that the allegations in Paragraph 718 refers to the drug Lupron<sup>®</sup>, any response would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron<sup>®</sup>.

719.-769. The allegations in Paragraphs 719-769 are directed to other defendants and require no response from TAP. To the extent a response is deemed to be required, TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 719-769.

770.-772. To the extent the allegations in Paragraphs 770-772 are directed at TAP, TAP denies them, except TAP denies knowledge or information sufficient to form a belief as to the truth of the allegation that the Counties’ Medicaid programs “spent over \$20 billion for defendants’ drugs from 1992 – 2005.” TAP specifically denies that it was involved in any “false price reporting scheme” or “misconduct,” or that it has been “unjustly enriched.” To the extent the allegations in Paragraphs 770-772 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

773.-790. To the extent the allegations in Paragraphs 773-790 are directed at TAP, TAP denies them. TAP further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraphs 773-790 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 786 refer to *The Pink Sheet*, that document speaks for itself, and any characterizations thereof are denied.

#### **COUNT I**

##### **VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)**

791. In response to Paragraph 791, TAP repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 790.

792.-800. To the extent the allegations in Paragraphs 792-800 are directed at TAP, TAP states that the Court has dismissed them. To the extent that a response is still required, TAP denies the allegations as to itself. To the extent the allegations in Paragraphs 792-800 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

#### **COUNT II**

##### **VIOLATION OF N.Y. SOCIAL SERVICES LAW 367-a(7)(d) (FAILURE TO COMPLY WITH STATE MEDICAID REBATE PROVISION)**

801. In response to Paragraph 801, TAP repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 800.

802.-807. To the extent the allegations in Paragraphs 802-807 are directed at TAP, TAP states that the Court has dismissed them. To the extent that a response is still required, TAP denies the allegations as to itself. To the extent the allegations in Paragraphs 802-807 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

### **COUNT III**

#### **VIOLATION OF NEW YORK SOCIAL SERVICES LAW 145-b (OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS)**

808. In response to Paragraph 808, TAP repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 807.

809. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 809. To the extent the allegations in Paragraph 809 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

810.-813. To the extent the allegations in Paragraphs 810-813 are directed at TAP, TAP denies them. To the extent the allegations in Paragraphs 810-813 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 810-813 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 810-813 contain legal conclusions, no response is required.

### **COUNT IV**

#### **VIOLATION OF NEW DEPARTMENT OF HEALTH REGULATIONS 18 N.Y.C.R.R. 512.2(b)4) and (5)**

814. In response to Paragraph 814, TAP repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 813.

815.-817. To the extent the allegations in Paragraphs 815-817 are directed at TAP, TAP states that the Court has dismissed them. To the extent that a response is still required, TAP denies the allegations as to itself. To the extent the allegations in Paragraphs 814-817 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

## **COUNT V**

### **BREACH OF CONTRACT**

808. In response to Paragraph 818, TAP repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 817.

819.-830. To the extent the allegations in Paragraphs 819-830 are directed at TAP, TAP states that the Court has dismissed them. To the extent that a response is still required, TAP denies the allegations as to itself. To the extent the allegations in Paragraphs 819-830 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

## **COUNT VI**

### **UNFAIR TRADE PRACTICES (Violations of N.Y. Gen. Bus. Law 349 *et seq.*)**

831. In response to Paragraph 831, TAP repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 830.

832.-835. To the extent the allegations in Paragraphs 832-835 and the exhibits referenced therein are directed at TAP, TAP denies them. To the extent the allegations in Paragraphs 832-

835 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 832-835 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

836.-837. TAP admits that it paid approximately \$875 million in fines and civil settlements in connection with the marketing and sale of the drug Lupron<sup>®</sup>. TAP further states that to the extent that Paragraphs 836-37 refer to the drug Lupron<sup>®</sup>, any response to these allegations would be premature given that there is a pending motion to dismiss with respect to all claims against TAP related to the drug Lupron<sup>®</sup>. To the extent any remaining allegations in Paragraphs 836-837 are directed at TAP, TAP denies them. To the extent the allegations in Paragraphs 836-837 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 836-837 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

838.-839. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto are directed at TAP, TAP denies them. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto contain legal conclusions, no response is required.

## **COUNT VII**

### **FRAUD**



84. In response to Paragraph 840, TAP repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 839.

841.-843. To the extent the allegations in Paragraphs 841-843 and the exhibits referenced therein are directed at TAP, TAP denies them. To the extent the allegations in Paragraphs 841-843 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth.

844. TAP denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 844. To the extent the allegations in Paragraph 844 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

845. To the extent the allegations in Paragraph 845 are directed at TAP, TAP denies them. To the extent the allegations in Paragraph 845 are directed at parties other than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 845 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 845 contain legal conclusions, no response is required.

## **COUNT VIII**

### **UNJUST ENRICHMENT**

846. In response to Paragraph 846, TAP repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 845.

847.-849. To the extent the allegations in Paragraphs 847-849 are directed at TAP, TAP denies them. To the extent the allegations in Paragraphs 847-849 are directed at parties other

than TAP, TAP denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 847-849 contain legal conclusions, no response is required.

850.-858. TAP denies that the Counties are entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 850-858 of the Complaint.

**WHEREFORE**, TAP demands judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

### **AFFIRMATIVE DEFENSES**

TAP reasserts and incorporates herein by reference the assertions of Paragraphs 1 through 858 hereof.

#### **First Affirmative Defense**

Plaintiffs fail to state a claim against TAP upon which relief may be granted.

#### **Second Affirmative Defense**

This Court lacks subject matter jurisdiction over all or some of the claims asserted by the Plaintiffs.

**Third Affirmative Defense**

This Court lacks subject matter jurisdiction based on the doctrines of exclusive and primary jurisdiction and failure to exhaust administrative remedies.

**Fourth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because they did not rely on any alleged misrepresentations or fraud by TAP. Plaintiffs knew that providers could obtain TAP drugs at prices below AWP prior to the relevant time period stated in the Complaint.

**Fifth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**Sixth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the filed rate doctrine.

**Seventh Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the state action doctrine.

**Eighth Affirmative Defense**

Plaintiffs' claims are barred because Plaintiffs lack standing to assert all or some of their claims in this lawsuit, including the asserted claims against TAP.

**Ninth Affirmative Defense**

The Plaintiffs and/or their agents knew and were aware that AWP was not an average wholesale price or the actual acquisition cost of drugs. Legal and equitable principles preclude this action for damages and injunctive relief, and the Due Process Clause of the U.S. Constitution and Section 6 of the New York Constitution preclude Plaintiffs from bringing claims and seeking damages as alleged in the Complaint.

**Tenth Affirmative Defense**

To the extent Plaintiffs or the State of New York obtain recovery in any other case predicated on the same factual allegations, Plaintiffs are barred from seeking recovery against TAP based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

**Eleventh Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by TAP in judicial, legislative, or administrative proceedings of any kind or at any level of government.

**Twelfth Affirmative Defense**

The Plaintiffs' claims against TAP are misjoined with the Plaintiffs' claims against other defendants and must be severed.

**Thirteenth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiffs' claims.

**Fourteenth Affirmative Defense**

The Plaintiffs' claims are barred, in whole or in part, because they conflict with federal statutes and regulations that comprise a comprehensive regulatory regime governing the amounts paid to providers for Medicare Part B-covered drugs.

**Fifteenth Affirmative Defense**

The Plaintiffs' claims against TAP for injunctive relief were mooted by the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

**Sixteenth Affirmative Defense**

The Plaintiffs' claims are preempted by the dormant Commerce Clause of the United States Constitution.

**Seventeenth Affirmative Defense**

The Plaintiffs' claims are preempted by the Commerce Clause of the United States Constitution.

**Eighteenth Affirmative Defense**

The Plaintiffs' claims against TAP are barred, in whole or in part, because TAP has complied with all applicable regulations of the federal and state governments.

**Nineteenth Affirmative Defense**

The Plaintiffs' claims are barred, in whole or in part, because they violate TAP's rights under the due process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of New York, insofar as the Plaintiffs seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Twentieth Affirmative Defense**

The Plaintiffs' claims against TAP are barred, in whole or in part, because the Plaintiffs have no standing or capacity to bring some or all of the claims raised in this suit to recover Medicaid or Medicare expenditures or to seek injunctive relief.

**Twenty-First Affirmative Defense**

The Plaintiffs' claims against TAP are barred, in whole or in part, because TAP did not make any false statements to the Plaintiffs or any of the agencies, departments, or citizens for whom the Plaintiffs are seeking relief. As to any statement asserted against TAP that the Plaintiffs allege to be false or misleading, TAP had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Twenty-Second Affirmative Defense**

The Plaintiffs' claims against TAP are barred because TAP did not directly or indirectly engage in any conduct in violation of state or federal law.

**Twenty-Third Affirmative Defense**

The Plaintiffs' claims are barred, in whole or in part, because TAP's conduct was neither "deceptive," "misleading," "unlawful," nor "illegal."

**Twenty-Fourth Affirmative Defense**

The Plaintiffs are barred from recovery because the representations and actions alleged by the Plaintiffs were not, and are not, material, in that they were not, and are not, likely to affect the decisions or conduct of Plaintiffs, or to have caused consumers or Third Party Payors to have chosen differently, but for such alleged representations or actions, in light of the information available and known to consumers and Third Party Payors, and in that the alleged representations and actions were not likely to mislead consumers or Third Party Payors acting reasonably under the circumstance.

**Twenty-Fifth Affirmative Defense**

Some or all of the Plaintiffs' claims for injunctive relief against TAP are barred by the doctrines of *in pari delicto* and/or unclean hands.

**Twenty-Sixth Affirmative Defense**

The Plaintiffs' claims against TAP are barred, in whole or in part, because the Plaintiffs suffered no damages as a result of the matters alleged in the Complaint.

**Twenty-Seventh Affirmative Defense**

The Plaintiffs' claims are barred, in whole or in part, because any injuries sustained by the Plaintiffs were the result of their own conduct or the intervening or superseding conduct of third parties. Any and all of the injuries or damages suffered by Plaintiffs resulted solely from conduct and/or conditions for which TAP is not responsible and for which it cannot be held liable. Alternatively, any injuries or damages suffered by Plaintiffs were not caused or contributed by any act or omission of TAP, but were caused solely by the acts of others for which TAP may not be held liable.

**Twenty-Eighth Affirmative Defense**

Plaintiffs' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated there under.

**Twenty-Ninth Affirmative Defense**

Plaintiffs' claims against TAP are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

**Thirtieth Affirmative Defense**

Plaintiffs fail to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against TAP contained in the Complaint.



**Thirty-First Affirmative Defense**

Any and all actions taken by TAP with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**Thirty-Second Affirmative Defense**

TAP's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs.

**Thirty-Third Affirmative Defense**

TAP denies that Plaintiffs have valid consumer protection claims against TAP under New York's Unfair Trade Practices Act. However, if such claims are found to exist, TAP pleads all available defenses under the Act.

**Thirty-Fourth Affirmative Defense**

To the extent that Plaintiffs attempt to seek equitable relief against TAP, Plaintiffs are not entitled to such relief because Plaintiffs have an adequate remedy at law.

**Thirty-Fifth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

**Thirty-Sixth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiffs have received and paid for medicines manufactured, marketed and sold by TAP after the filing of the complaint of Suffolk County.

**Thirty-Seventh Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Thirty-Eighth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, due to their failure to join indispensable parties.

**Thirty-Ninth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not suffered damages as a result of the matters alleged in the Complaint.

**Fortieth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs failed to mitigate damages, and that failure to mitigate damages should proportionately reduce Plaintiffs' recovery and the allocation of any fault, if any exists, attributable to TAP.

**Forty-First Affirmative Defense**

TAP is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs, with respect to the same alleged injuries.

**Forty-Second Affirmative Defense**

To the extent punitive damages are sought, Plaintiffs' punitive damages claims against TAP are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against TAP.

**Forty-Third Affirmative Defense**

To the extent punitive damages are sought, Plaintiffs' damages claims against TAP cannot be sustained because an award of punitive damages would violate the United States Constitution, Excessive Fines Clause of the Eighth Amendment, U.S. Const. amend. VIII and the Due Process Clause of the Fourteenth Amendment, U.S. Const. amend. XIV, § 1 and the analogous provisions contained in the Constitutions of the State of New York and any other States whose laws are or become relevant in the course of this lawsuit.

**Forty-Fourth Affirmative Defense**

The applicable statutory ceilings on recoverable damages must limit any damages recovered by the Plaintiffs from TAP.

**Forty-Fifth Affirmative Defense**

The Plaintiffs fail to allege facts or a cause of action against TAP sufficient to support a claim for compensatory damages, attorneys' fees and/or legal fees, or any other relief.

**Forty-Sixth Affirmative Defense**

TAP denies that it has engaged in any conduct that entitles the Plaintiffs to recover penalty assessments and avers that the Plaintiffs' Complaint fails to state a claim upon which penalty assessments may be awarded to the Plaintiff.

**Forty-Seventh Affirmative Defense**

The Plaintiffs' penalty assessment claims against TAP: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for penalty assessments against TAP; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of penalty assessments fail to give TAP prior notice of the conduct for which penalty assessments may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of TAP's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and the Constitution of the State of New York; (4) cannot be sustained because any award of penalty assessments exceeding the limits authorized by the laws or other comparable laws would violate TAP's due process and equal protection Rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and applicable state laws of New York; (5) cannot be sustained because an award of penalty assessments in this case, combined with any prior,

contemporaneous, or subsequent judgments against TAP for penalty assessments arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of TAP's medicines, would constitute impermissible multiple punishments for the same wrong in violation of TAP's due process and equal protection Rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law and statutory law of New York; (6) cannot be sustained because any award of penalty assessments without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate TAP's due process and equal protection Rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and public policies of New York; and (7) cannot be sustained because any award of penalty assessments, which are penal in nature, without according TAP the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the imposition of excessive fines would violate TAP's rights guaranteed by the Fourth, Fifth, Sixth, and Eighth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law and public policies of New York.

#### **Forty-Eighth Affirmative Defense**

The Plaintiffs' claim for penalty assessments against TAP cannot be sustained because an award of penalty assessments by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the

appropriate size of, a penalty assessments award; (2) is not adequately instructed on the limits of penalty assessments imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding penalty assessments, or determining the amount of an award of penalty assessments, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation, the residence, wealth, and corporate status of TAP; (4) is permitted to award penalty assessments under a standard for determining liability for penalty assessments that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes penalty assessments permissible; (5) is not properly instructed regarding the Plaintiffs' burden of proof with respect to each and every element of a claim for penalty assessments; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate TAP's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law and public policies of New York.

#### **Forty-Ninth Affirmative Defense**

The Plaintiffs' claim for penalty assessments against TAP cannot be sustained because an award of penalty assessments that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of penalty assessments that may be imposed, would: (1) violate TAP's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate TAP's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law and public policies of New York.

**Fiftieth Affirmative Defense**

The Plaintiffs fail to allege facts or a cause of action against TAP sufficient to support a claim for prejudgment interest or any other relief.

**Fifty-First Affirmative Defense**

The Plaintiffs' claims are barred, in whole or in part, with respect to any alleged overcharge or supracompetitive price because such supracompetitive price, if any, was absorbed in whole or in part by a person and/or entity that purchased the medicine directly, and/or an intermediate purchaser, and was not passed through to the Plaintiffs.

**Fifty-Second Affirmative Defense**

To the extent Plaintiffs are asserting claims for unjust enrichment, they are barred, in whole or in part, because Plaintiffs have no authority to bring such claims on behalf of themselves or the citizens of New York.

**Fifty-Third Affirmative Defense**

To the extent Plaintiffs are asserting claims for unjust enrichment, they are barred, in whole or in part, by contracts to which Plaintiffs and TAP are parties.

**Fifty-Fourth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of contributory and/or comparative fault because Plaintiffs' own actions or failures to act helped to bring about any injuries sustained.

**Fifty-Fifth Affirmative Defense**

TAP breached no legal duty to Plaintiffs, and the Revised First Amended Consolidated Complaint filed herein should be dismissed with all costs taxed to Plaintiffs.

**Fifty-Sixth Affirmative Defense**

Some or all of Plaintiffs' claims are barred by the Statute of Frauds.

**Fifty-Seventh Affirmative Defense**

Plaintiffs may not sue *parens patriae* when there is no express state statutory or common law authority to do so, and would unconstitutionally deprive TAP of its vested right in the application of the statutes of limitations to the otherwise time-barred putative claims of private citizens.

**Fifty-Eighth Affirmative Defense**

Plaintiffs lack the authority to assert the putative *parens patriae* claims on behalf of the citizens of New York.

**Fifty-Ninth Affirmative Defense**

The Plaintiffs' claims are barred as a result of TAP's provision to the state and First Data Bank beginning with the fourth quarter of 2001 of quarterly average sales price reports for its drugs pursuant to a Settlement Agreement between the state and TAP.



**Sixtieth Affirmative Defense**

To the extent the Complaint purports to allege claims relating to the drug Lupron<sup>®</sup>, those claims have been completely settled and released. First, in late 2001, the State of New York settled and released TAP from all Lupron<sup>®</sup>-related Medicaid claims that the State, including its Counties and the Plaintiffs, purportedly possessed. Second, to the extent the Plaintiffs are attempting to assert any other claims related to Lupron<sup>®</sup> on behalf of itself or its citizens, including Medicaid-related claims that purportedly matured after 2001, those claims have been fully and finally settled pursuant to a nationwide class-action settlement.

**Sixty-First Affirmative Defense**

TAP adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

**Sixty-Second Affirmative Defense**

TAP hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense.

**JURY DEMANDED**

A jury trial on all issues is hereby demanded.

Dated: October 26, 2007

/s/ Toni-Ann Citera

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Lee Ann Russo

Toni-Ann Citera

Rachael E. Philbin

JONES DAY

77 West Wacker Drive, Suite 3500

Chicago, IL 60601

Tel: (312) 782-3939

Fax: (312) 782-8585

*Counsel for Defendant TAP Pharmaceutical  
Products Inc.*

**CERTIFICATE OF SERVICE**

I, Rachael E. Philbin, an attorney, hereby certify that I caused a true and correct copy of the foregoing ANSWER AND AFFIRMATIVE DEFENSES to be served upon all counsel of record via LNFS, this 26th day of October, 2007.

/s/ Rachael E. Philbin

Rachael E. Philbin